REMARKS/ARGUMENTS

Claims 1-8, 10-12 and 17 are active.

Support for Claim 17 is found in the combination of Claims 1, 2, 4, and 6.

Claim 1 and 8 are amended for clarity thereby rendering the 112, second paragraph rejection no longer applicable.

Due to the maintained Restriction Requirement Claims 9 and 13-16 have been cancelled.

No new matter is added.

The rejection of the claims as obvious in view of WO 01/68058 (Beckert, also cited in the specification at page 2) or U.S. 5,643,602 (Ulmius).

Beckert already has a U.S. equivalent and is U.S. 6,632,454. Therefore, Applicants ask that the Office use this document as the English language equivalent in response to the Information Disclosure request at page 6 of the Action. U.S. 6,632,454 is listed on the attached PTO 1449 Form.

In Beckert, there is a multilayer formulation and may include budesonide (see col. 4, line 15, line 54 to col. 6, line 26). In Example 1 (as cited in the rejection), the cores are first sprayed with the binder (Kollidon 25) and then the layering powder (including the active, 5-aminosalicylic acid). In other words, Beckert uses Kollidon 25 as a binder for the core onto which the active ingredient (5 Aminosalicylic acid) is applied by powder layering.

Beckert does not describe binding the active, budesonide, with the binder but rather applies the binder and active separately. This is apparent from the manner in which Beckert describes the synthesis of the product in col. 2-3. core with active, inner and outer coating. Then in the Examples (col. 7), the cores were sprayed with the binder and the layering powder was added (i.e., separate addition).

Therefore, Beckert does not suggest providing an inner layer where the active is bound in a binder as in Claim 1. The specification at pages 5-6 discusses how one is to achieve such bound active in the binder, e.g., by forming a dispersion and or by melt extrusion. While these are "method" steps and the elected claims here are to a composition, the intent here is to show that what and how Beckert makes formulations does not necessarily result in an active (here budesonide) bound in a binder, noting that mere possibilities is an insufficient basis to conclude that what is done in the prior art is inherent to the claimed limitation at issue.

Second, Kollidon 25 is not an anionic polymer but a polyvinylpyrrolidon polymer which is neutral and therefore is not a polymer or copolymer with acidic groups (see Claim 1). See Kollidon 25 in the attached Technical information sheet.

The background section of the application concedes that coated budesonide formulations were known. In particular, the disclosure in WO 01/68058 is acknowledged at page 2 and also uses this disclosure to define preferred embodiments of certain aspects of the claimed formulation (see pages 15-18). As discussed at the bottom of page 2, budesonide formulations have the problem of low solubility. However, as discussed at the top of page 4 providing a binder that is a polymer or copolymer with acidic groups provides that stability.

Reconsideration and withdrawal of the rejection is requested.

To the Ulmius based rejection. Ulmius also describes a multilayer pharmaceutical formulation with budesonide as one example of the active (see col. 3 and Example 1 in col. 8). The active glucocorticosteroid can be in the seed (col. 5, lines 7-8) or applied on the seed in the first layer with polymers such as Eudragit™-type polymers. In Example 1 of Ulmius, budesonide is combined with Aquacoat ECD 30 (which we understand to be a type of

Ethylcellulose Aqueous Dispersion) and sprayed onto the sugar core and the coated with a Eudragit L100-55 coating.

In example 1, Ulmius uses Aquacoat® ESD as a binder for budesonide. Aquacoat® ESD is not an anionic polymer but ethylcellulose which is a neutral polymer. (see attached publicly available information concerning Aquacoat® ESD). There is also no inner coating layer in Ulmius. Therefore Ulmius neither describe nor suggests a polymeric binder nor the layer composition as claimed.

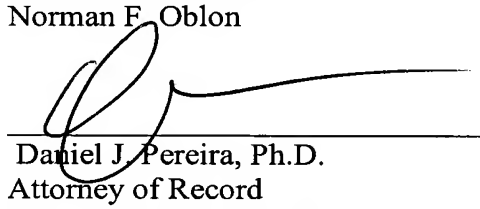
Notwithstanding the differences in terms of layers, the Examiner deems that providing a further layer on the two layers in Example 1 would have been obvious. As Ulmius does not make any mention of that, the conclusion in the rejection is unsupported and lacks factual basis for the specific types of formulations provided in the claims. Indeed, as explained above and in the specification, by providing budesonide with the specific selection of binders that provide the dissolution results discussed in the specification and stability of the active budesonide in the formulation is achieved.

Reconsideration and withdrawal of the rejection is requested.

A Notice of Allowance is also requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Daniel J. Pereira, Ph.D.
Attorney of Record
Registration No. 45,518

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)